REMARKS

Claims 36-46, 52 and 53 are currently pending in this application. Claims 1-35 were cancelled and claims 36-51 were added by Preliminary Amendment. Claims 47-51 have been withdrawn from consideration in view of an earlier Restriction Requirement, and claims 52 and 53 were added in a previous Amendment dated April 16, 2004. This Amendment cancels claim 53 and amends claims 40 and 42. Claims 38 and 40 have been amended to correct grammatical errors. Claim 42 has been amended to specify further that the starch is homogeneously distributed throughout the rubber latex. Support for the amendment to claim 42 can be found in the specification and claims as originally filed. No new matter has been added. This added language to claim 42 limits further the way the starch is distributed into the liquid rubber latex in the claimed article and amplifies the distinction between the claim and the teachings of the prior art in a way that places the case in condition for immediate allowance. In view of the above, entry of the amendment to claim 42 is respectfully requested.

The Examiner has withdrawn the previous art rejections of claims 36-46 and has newly rejected the claims based upon prior art, namely, U.S. Patent No. 5,691,446 to Dove (hereinafter "the Dove patent").

The Examiner has rejected claims 40 and 53 under 35 U.S.C. § 112, second paragraph, for indefiniteness. Claim 53 has been cancelled and, therefore, the rejection of claim 53 is moot. The Examiner asserts that the language "wherein the modified starch is obtainable by gelatinizing the starch in an extruder and subsequently cross-linking the starch with glyoxal" in independent claim 40 does not limit further the modified starch used in claim 39, from which claim 40 depends. Notwithstanding this assertion, the additional language "wherein the allergen activity of said rubber latex is maximally 15%" in claim 40 does limit further the allergen activity of the rubber latex (i.e., maximally 40%) in claim 39. Therefore, claim 40 is in proper dependent form. In view of the foregoing, withdrawal of the rejection of claim 40 is respectfully requested.

The present invention, as claimed in independent claim 36, is directed to a method for reducing the allergen activity of rubber latex for use in a rubber latex article. The method comprises incorporating starch into the liquid rubber latex before the article is formed. The starch is homogeneously distributed throughout the rubber latex, thus forming

both physical and chemical bonds with the amino and acid groups of the rubber latex, thereby binding potentially allergenic latex proteins. As discussed in detail below, none of the cited prior art references teaches or suggests incorporating a starch into the liquid rubber latex before forming the article.

The Examiner has finally rejected claims 36-41 and 52 under 35 U.S.C. § 103(a) for obviousness over U.S. Patent No. 4,143,109 to Stockum (hereinafter "the Stockum patent") in view of the Dove patent. The Examiner asserts that the Stockum patent teaches a method for producing rubber latex in combination with a cross-linked corn starch used in medical gloves and other articles. Specifically, the Examiner asserts that the Stockum patent discloses a method used to cover a preformed latex glove, wherein a part of the fluid latex is mixed with cross-linked corn starch. The Examiner concedes that the Stockum patent does not provide an explicit example of how the rubber latex article is formed from the mixture of starch and rubber latex. The Examiner has combined the Dove patent with the Stockum patent for the asserted teaching of a method for producing reduced allergen rubber latex articles using biopolymers (screening agents) which can be incorporated into the rubber latex via manufacturing protocols such as dip-forming. Therefore, the Examiner concludes that one skilled in the art would have a reasonable expectation for success in combining the Stockum patent and the Dove patent to obtain a rubber latex article comprising an amount of corn starch or modified corn starch. Applicants respectfully disagree with the Examiner's assertions.

The Stockum patent is directed to a method of making a medical glove which may be donned easily without the use of additional lubricants, such as loose dusting powders (e.g., cross-linked corn starch), which may cause granuloma and other postoperative complications during surgical procedures (column 1, lines 9-23). The method comprises the steps of dipping a glove form 30 having a general contour of a human hand in a composition 34 of natural rubber latex, thus forming an outer layer 15 of glove 10 (column 3, lines 31-42). Next, a second layer is deposited onto layer 15 of glove 10 by dipping glove 10 into a suspension 42 comprising elastomeric material 20 and particulate matter 22 (column 3, lines 52-55). The particulate matter 22 used to form the suspension 42 is an epichlorohydrin cross-linked corn starch (column 4, lines 21-23). The layers are then cured and the glove 10 is stripped from the form 30 and reversed so that the skin-contacting layer can receive the

second layer having particulate matter. The glove 10 in the Stockum patent is already formed before the second layer having the starch is applied. The particulate matter 22 is randomly distributed throughout the inner layer, so that portions 22a of the starch particles are partially exposed on the inner, skin-contacting surface of the glove (column 3, lines 11-16 and column 5, lines 18-20). Therefore, the problems of allergen activity of the latex rubber still exist.

The Dove patent is directed to a method for reducing allergenicity of natural rubber latex articles by adding screening reagents to a natural rubber latex emulsion. Natural rubber latex articles, such as gloves, can be formed through a dip-forming process in which an article-forming mandrel is dipped into a latex emulsion bath followed by rinsing and drying/curing steps prior to removal of the latex article from the mandrel (column 8, lines 17-22). The Dove patent discloses that it may be possible to add the screening reagents to the natural rubber latex emulsion as a preliminary manufacturing step, however, this may not be desirable if the preservation of antioxidant compounds and preservatives are desired (column 9, lines 8-12). The primary strength or objective of the Dove patent is to maintain the normally occurring beneficial properties of natural rubber latex (column 7, lines 63-65) and, therefore, the screening agents used should not affect the biocompatability or molecular structure of the base rubber polymer. A list of the exemplary chemical screening agents includes diepoxies, dialdehydes, dienes, bismalimides and diisocyanates (column 11, lines 8-17). The Dove patent does not disclose a starch. As discussed below in detail, there is no teaching, suggestion or motivation in either the Stockum patent or the Dove patent, alone or in combination, that teaches incorporating a <u>starch</u> into the liquid rubber latex before the article is formed in order to reduce the allergen activity of the <u>rubber</u> latex.

The motivation to modify the prior art must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. The motivation cannot be derived from Applicants' specification. In the Dove patent, the list of screening reagents does not include starch. In fact, the Dove patent teaches away from the use of screening reagents that have an adverse effect on the normally occurring beneficial properties of natural rubber latex. The substitution of a starch as disclosed in the Stockum patent for a screening reagent would change the chemical structure of the natural rubber latex (i.e., stiffen the rubber latex), which is contrary to the objective of the Dove patent. It has also been determined that the more hydrophobic or the more

hydrophilic screening reagents may be less effective under some circumstances than screening reagents that exhibit both mildly hydrophilic and mildly hydrophobic characteristics (column 12, lines 7-11 of the Dove patent). Because starches are high molecular weight, complex carbohydrates that are insoluble in water (i.e., completely hydrophobic), the Dove patent teaches away from incorporating a starch into natural rubber latex. Therefore, absent hindsight, there is no desire or incentive in the Dove patent to substitute a starch for a screening reagent.

The Examiner contends that the motivation to produce a "powderless glove" for surgery in the Stockum patent comes from the fact that the allergen activity caused by a powdery starch in a rubber latex glove is avoided. Although the allergen activity from the starch is reduced in the Stockum patent, the problem of rubber latex allergenic reactions still exists. In contrast, although rubber latex allergenic reactions are reduced due to the screening reagents in the Dove patent, the absence of starch avoids the problem of allergenic reactions from starch in latex articles. Therefore, there is no incentive in the Dove patent to introduce possible allergenic reactions from starch into a latex article that did not exist in the first place. Furthermore, one skilled in the rubber latex art would not incorporate a material, which is known to both stiffen rubber latex articles and cause allergenic reactions, into natural liquid rubber latex for the purpose of reducing allergenic reactions caused by the rubber latex itself. Therefore, absent hindsight, there is no teaching, suggestion or motivation in either the Stockum patent or the Dove patent, alone or in combination, that teaches incorporating a starch into the liquid rubber latex before the article is formed.

Furthermore, because the objective of the Stockum patent (i.e., reduction of starch allergen activity) is completely different from the objective of the Dove patent (i.e., reduction of rubber latex allergen activity), one skilled in the art would not have combined these two references together in the first place.

In view of the foregoing, reconsideration and withdrawal of the rejection of claims 36-41 and 52 are respectfully requested.

The Examiner has finally rejected claims 42-46 and 53 under 35 U.S.C. § 103(a) for obviousness over the Dove patent in view of the Stockum patent for the reasons discussed on pages 6-8 of the final Office Action. Claim 53 has been cancelled. In response, independent claim 42 has been amended, thus limiting the claim to an amount of starch "that

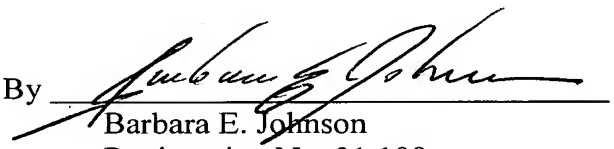
is homogeneously distributed throughout the rubber latex." Support for the amendment to claim 42 can be found, for example, on page 19, lines 1-2 and 22-27 of the present specification.

As previously discussed, the Dove patent does not disclose the use of a starch, and the starch particles of the Stockum patent are partially exposed on the inner, skin-contacting surface of the glove. Therefore, none of the prior art references teaches or suggests an amount of starch homogeneously distributed throughout the rubber latex. Because claims 43-46 depend either directly or indirectly from independent claim 42, and for the reasons discussed above in connection with independent claim 36, Applicants believe that claims 42-46 are distinguishable over the Dove patent and the Stockum patent. Accordingly, reconsideration and withdrawal of the rejection of claims 42-46 are respectfully requested.

In view of the foregoing, Applicants believe that claims 36-46 and 52 are patentable over the prior art of record and are in condition for allowance. Entry of the amendments to claims 38, 40 and 42 is respectfully requested.

Respectfully submitted,

WEBB ZIESENHEIM LOGSDON
ORKIN & HANSON, P.C.

By 

Barbara E. Johnson
Registration No. 31,198
Attorney for Applicants
700 Koppers Building
436 Seventh Avenue
Pittsburgh, Pennsylvania 15219-1818
Telephone: 412-471-8815
Facsimile: 412-471-4094
E-mail: webblaw@webblaw.com